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*Admitted only in Maryland
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•Practice Limited to Federal Agencies

January 25, 2005

WRITER'S DIRECT NUMBER:
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ANNS@SKGF.COM

Commissioner for Patents
PO Box 1450
Alexandria, VA 22313-1450

Re: U.S. Utility Patent Application
Appl. No. 10/820,036; Filed: April 8, 2004
For: **Semi-Synthetic Saponin Analogs with Carrier and Immune Stimulatory Activities for DNA and RNA Vaccines**
Inventor: Dante J. Marciani
Our Ref: 1635.0190002/JMC/AES

Sir:

Applicant submits the following documents for appropriate action by the U.S. Patent and Trademark Office:

1. Information Disclosure Statement;

2. Fourteen (14) pages of Form PTO-1449 citing fifty-four (54) documents;

3. Copies of forty-one (41) cited documents; and

4. One (1) return postcard.

It is respectfully requested that the attached postcard be stamped with the date of filing of these documents, and that it be returned to our courier.

The U.S. Patent and Trademark Office is hereby authorized to charge any fee deficiency, or credit any overpayment, to our Deposit Account No. 19-0036. If extensions of time under 37 C.F.R. § 1.136 other than those otherwise provided for herewith are required to prevent

abandonment of the present patent application, then such extensions of time are hereby petitioned, and any fees therefor are hereby authorized to be charged to our Deposit Account No. 19-0036.

Respectfully submitted,

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.

Ann E. Summerfield
Attorney for Applicant
Registration No. 47,982

AES/law
Enclosures

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JAN 25 2005
PATENT & TRADEMARK OFFICE

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:	Confirmation No.: 7580
Dante J. Marciani	Art Unit: 1653
Appl. No.: 10/820,036	Examiner: *To be assigned*
Filed: April 8, 2004	Atty. Docket: 1635.0190002/JMC/AES
For: **Semi-Synthetic Saponin Analogs with Carrier and Immune Stimulatory Activities for DNA and RNA Vaccines**	

Information Disclosure Statement

Commissioner for Patents
PO Box 1450
Alexandria, VA 22313-1450
Sir:

Listed on accompanying Form PTO-1449 are documents that may be considered material to the examination of this application, in compliance with the duty of disclosure requirements of 37 C.F.R. §§ 1.56, 1.97 and 1.98.

Copies of documents **AA1-AK1** and **AA2-AB2** are not provided in accordance with the Changes To Support Implementation of the United States Patent and Trademark Office 21st Century Strategic Plan, effective October 21, 2004, which states "section 1.98(a)(2)(i) is amended to eliminate the requirement in paragraph (a)(2)(i) for a copy of each U.S. patent or U.S. patent application publication listed in an IDS in a patent application regardless of the filing date of the application." A copy of each other document is provided.

The Examiner's attention is directed to the following co-pending U.S. Patent Applications, which are directed to related technical subject matter:

U.S. Patent Application No. 10/114,465, Marciani, D.J., filed April 3, 2002, published as U.S. Patent Appl. Pub. No. 2002/0150585 A1 on October 17, 2002, and submitted herewith as document **AA2**; and

U.S. Patent Application No. 10/859,577, Marciani, D.J., filed June 3, 2004, published as U.S. Patent Appl. Pub. No. 2004/0220142 A1 on November 4, 2004, and submitted herewith as document **AB2**.

The identification of these U.S. Patent Applications is not to be construed as a waiver of secrecy as to these applications now or upon issuance of the present application as a patent. The Examiner is respectfully requested to consider the cited applications and the art cited therein during examination.

Where the publication date of a listed document does not provide a month of publication, the year of publication of the listed document is sufficiently earlier than the effective U.S. filing date and any foreign priority date so that the month of publication is not in issue. Applicant has listed publication dates on the attached Form PTO-1449 based on information presently available to the undersigned. However, the listed publication dates should not be construed as an admission that the information was actually published on the date indicated.

Applicant reserves the right to establish the patentability of the claimed invention over any of the information provided herewith, and/or to prove that this information may not be prior art, and/or to prove that this information may not be enabling for the teachings purportedly offered.

This statement should not be construed as a representation that a search has been made, or that information more material to the examination of the present patent application does not

exist. The Examiner is specifically requested not to rely solely on the material submitted herewith.

This Information Disclosure Statement is being filed before the mailing date of a first Office Action on the merits. No statement or fee is required.

It is respectfully requested that the Examiner initial and return a copy of the enclosed Form PTO-1449, and indicate in the official file wrapper of this patent application that the documents have been considered.

The U.S. Patent and Trademark Office is hereby authorized to charge any fee deficiency, or credit any overpayment, to our Deposit Account No. 19-0036.

Respectfully submitted,

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.

Ann E. Summerfield
Attorney for Applicant
Registration No. 47,982

Date: January 25, 2005

1100 New York Avenue, N.W.
Washington, D.C. 20005-3934
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OIPE JC25 JAN 25 2005 PATENT & TRADEMARK OFFICE

FORM PTO-1449

INFORMATION DISCLOSURE STATEMENT

ATTY. DOCKET NO.	APPLICATION NO.
1635.0190002/JMC/AES	10/820,036
APPLICANT	
Dante J. Marciani	
FILING DATE	ART UNIT
April 8, 2004	1653

U.S. PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB-CLASS	FILING DATE
	AA1	4,713,339	12/15/1987	Levinson *et al.*			01/19/1983
	AB1	4,897,355	01/30/1990	Eppstein *et al.*			10/29/1987
	AC1	4,965,196	10/23/1990	Levinson *et al.*			09/24/1987
	AD1	5,057,540	10/15/1991	Kensil *et al.*			08/27/1990
	AE1	5,264,618	11/23/1993	Felgner *et al.*			04/16/1991
	AF1	5,273,965	12/28/1993	Kensil *et al.*			07/02/1992
	AG1	5,583,112	12/10/1996	Kensil *et al.*			07/02/1992
	AH1	5,861,397	01/19/1999	Wheeler			10/03/1996
	AI1	5,977,081	11/02/1999	Marciani			05/20/1998
	AJ1	6,080,725	06/27/2000	Marciani			04/13/1999
	AK1	6,262,029	07/17/2001	Press *et al.*			08/13/1999

FOREIGN PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB-CLASS	TRANSLATION
	AL1	WO 02/102407	12/27/2002	WIPO			Yes No
	AM						Yes No
	AN						Yes No
	AO						Yes No
	AP						Yes No

OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

	AR	1	Altman-Hamamdzic, S., *et al.*, "Expression of β-galactosidase in mouse brain: utilization of a novel nonreplicative Sindbis virus vector as a neuronal gene delivery system," *Gene Ther. 4*:815-822, Nature Publishing Group (1997)
	AS	1	ApSimon, J.W., *et al.*, "Saponins from Marine Invertebrates," *Stud. Org. Chem. 17*:273-286, Elsevier (1984)
	AT	1	Behr, J-P., *et al.*, "Efficient gene transfer into mammalian primary endocrine cells with lipopolyamine-coated DNA," *Proc. Natl. Acad. Sci. USA 86*:6982-6986, National Academy of Sciences (1989)

EXAMINER	DATE CONSIDERED

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.

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FORM PTO-1449

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ATTY. DOCKET NO.	APPLICATION NO.
1635.0190002/JMC/AES	10/820,036
APPLICANT: Dante J. Marciani	
FILING DATE: April 8, 2004	ART UNIT: 1653

U.S. PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB-CLASS	FILING DATE
	AA2	2002/0150585	10/17/2002	Marciani			04/03/2002
	AB2	2004/0220142	11/04/2004	Marciani			06/03/2004
	AC						
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FOREIGN PATENT DOCUMENTS

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	AL						Yes No
	AM						Yes No
	AN						Yes No
	AO						Yes No
	AP						Yes No

OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

	AR	2	Bomford, R., *et al.*, "Adjuvanticity and ISCOM formation by structurally diverse saponins," *Vaccine 10*:572-577, Elsevier (1992)
	AS	2	Boyer, J., *et al.*, "Protection of chimpanzees from high-dose heterologous HIV-1 challenge by DNA vaccination," *Nat. Med. 3*:526-532, Nature Publishing Group (1997)
	AT	2	Boyle, J.S., *et al.*, "DNA immunization: Induction of higher avidity antibody and effect of route on T cell cytotoxicity," *Proc. Nat. Acad. Sci. USA 94*:14626-14631, National Academy of Sciences (1997)

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	AL						Yes No
	AM						Yes No
	AN						Yes No
	AO						Yes No
	AP						Yes No

OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

	AR	3	Chang, K.L.B., *et al.*, "Kinetics and Products of the Degradation of Chitosan by Hydrogen Peroxide," *J. Agric. Food Chem. 49*:4845-4851, American Chemical Society (2001)
	AS	3	Dalsgaard, K., "A Study of the Isolation and Characterization of the Saponin Quil A. Evaluation of its Adjuvant Activity, with a Special Reference to the Application in the Vaccination of Cattle Against Foot-and-Mouth Disease," *Acta Vet. Scand. 19 (Suppl. 69)*:1-40, Danske Dyrlageforenging (1978)
	AT	3	Dalsgaard, K., "Saponin Adjuvants," *Arch. Gesamte Virusforsch. 44*:243-254, Springer-Verlag (1974)

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	AL						Yes No
	AM						Yes No
	AN						Yes No
	AO						Yes No
	AP						Yes No

OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

	AR	4	Davis, H.L., *et al.*, "Direct gene transfer in skeletal muscle: plasmid DNA-based immunization against the hepatitis B virus surface antigen," *Vaccine 12*:1503-1509, Elsevier (1994)
	AS	4	Dow, S.W., *et al.*, "Lipid-DNA Complexes Induce Potent Activation of Innate Immune Responses and Antitumor Activity When Administered Intravenously," *J. Immunol.* 163:1552-1561, American Association of Immunologists (1999)
	AT	4	Felgner, P.L., and Ringold, G.M., "Cationic liposome-mediated transfection," *Nature 337*:387-388, Nature Publishing Group (1989)

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	AL						Yes No
	AM						Yes No
	AN						Yes No
	AO						Yes No
	AP						Yes No

OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

	AR	5	Felgner, P.L., *et al.*, "Lipofection: A highly efficient, lipid-mediated DNA-transfection procedure," *Proc. Natl. Acad. Sci. USA 84*:7413-7417, National Academy of Sciences (1987)
	AS	5	Gramzinski, R., *et al.*, "Immune Response to a Hepatitis B DNA Vaccine in *Aotus* Monkeys: A Comparison of Vaccine Formulation, Route, and Method of Administration," *Mol. Med. 4*:109-118, Blackwell Scientific Publications (1998)
	AT	5	Häcker, G., *et al.*, "Activation of the immune system by bacterial CpG-DNA," *Immunology 105*:245-251, Blackwell Scientific Publications (March 2002)

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	AL						Yes No
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	AO						Yes No
	AP						Yes No

OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

	AR	6	Higuchi, R., and Komori, T., "Structures of Compounds Derived from the Acyl Moieties of Quillajasaponin," *Phytochemistry 26*:2357-2360, Pergamon Press (1987)
	AS	6	Higuchi, R., *et al.*, "An Acylated Triterpenoid Saponin from *Quillaja Saponaria*," *Phytochemistry 27*:1165-1168, Pergamon Press (1988)
	AT	6	Higuchi, R., *et al.*, "Structure of Deacylsaponins Obtained from the Bark of *Quillaja Saponaria*," *Phytochemistry 26*:229-235, Pergamon Press (1987)

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	AL						Yes No
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OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

	AR	7	Hostettmann, K., *et al.,* "Saponins," *Methods Plant Biochem. 7*:435-471, Academic Press (1991)
	AS	7	Kensil, C.R., *et al.*, "Separation and Characterization of Saponins with Adjuvant Activity from *Quillaja saponaria* Molina Cortex," *J. Immunol. 146*:431-437, American Association of Immunologists (1991)
	AT	7	Kensil, C.R., *et al.,* "Structure/Function Relationship in Adjuvants from *Quillaja saponaria* Molina," *Vaccines 92*:35-40, Cold Spring Harbor Laboratory Press (1992)

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	AP						Yes No

OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

	AR	8	Klinman, D.M., *et al.*, "CpG motifs present in bacterial DNA rapidly induce lymphocytes to secrete interleukin 6, interleukin 12, and interferon γ," *Proc. Natl. Acad. Sci. USA 93*:2879-2883, National Academy of Sciences (1996)
	AS	8	Korman, A.J., *et al.*, "Expression of human class II major histocompatibility complex antigens using retrovirus vectors," *Proc. Nat. Acad. Sci. USA 84*:2150-2154, National Academy of Sciences (1987)
	AT	8	Lacaille-Dubois, M.A., and Wagner, H., "A review of the biological and pharmacological activities of saponins," *Phytomedicine 2*:363-386, Gustav Fischer Verlag (1996)

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	AP						Yes No

OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

	AR	9	Massiot, G., and Lavaud, C., "Structural Elucidation of Saponins," *Stud. Nat. Prod. Chem. 15*:187-224, Elsevier Science B.V. (1995)
	AS	9	Pillion, D.J., *et al.*, "Structure-Function Relationship among *Quillaja* Saponins Serving as Excipients for Nasal and Ocular Delivery of Insulin," *J. Pharm. Sci. 85*:518-524, American Pharmaceutical Association (1996)
	AT	9	Press, J.B., *et al.*, "Structure/Function Relationships of Immunostimulating Saponins," *Stud. Nat. Prod. Chem. 24*:131-174, Elsevier (2000)

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OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

	AR	10	Price, K.R., *et al.*, "The Chemistry and Biological Significance of Saponins in Foods and Feedingstuffs," *CRC Crit. Rev. Food Sci. Nutr. 26*:27-135, CRC Press (1987)
	AS	10	Ren, T., *et al.*, "Synthesis of bifunctional cationic compound for gene delivery," *Tetrahedron Lett. 42*:1007-1010, Pergamon Press (2001)
	AT	10	Sahu, N.P., *et al.*, "Triterpenoid Saponins from *Gymnema sylvestre*," *Phytochemistry 41*:1181-1185, Pergamon Press Ltd. (1996)

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OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

	AR	11	Sasaki, S., *et al.*, "Induction of Systemic and Mucosal Immune Responses to Human Immunodeficiency Virus Type 1 by a DNA Vaccine Formulated with QS-21 Saponin Adjuvant via Intramuscular and Intranasal Routes," *J. Virol. 72*:4931-4939, American Society for Microbiology (1998)
	AS	11	Schöpke, Th., and Hiller, K., "Triterpenoid saponins. Part 6," *Die Pharmazie 45*:313-342, Verlag Pharmazautischer (1990)
	AT	11	Schrijver, R.S., *et al.*, "Immunization of cattle with a BHV1 vector vaccine or a DNA vaccine both coding for the G protein of BRSV," *Vaccine 15*: 1908-1916, Elsevier (1997)

EXAMINER	DATE CONSIDERED

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FORM PTO-1449 INFORMATION DISCLOSURE STATEMENT	ATTY. DOCKET NO. 1635.0190002/JMC/AES	APPLICATION NO. 10/820,036
	APPLICANT Dante J. Marciani	
	FILING DATE April 8, 2004	ART UNIT 1653

U.S. PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB-CLASS	FILING DATE
	AA						
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FOREIGN PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB-CLASS	TRANSLATION
	AL						Yes No
	AM						Yes No
	AN						Yes No
	AO						Yes No
	AP						Yes No

OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

	AR	12	Shibata, S., "Saponins with Biological and Pharmacological Activity," in *New Natural Products and Plant Drugs with Pharmacological, Biological or Therapeutical Activity,* Wagner, H., and Wolff, P., eds., Springer-Verlag, Berlin, DE, pp. 177-196 (1977)
	AS	12	Siders, W.F., *et al.,* "Tumor Treatment with Complexes of Cationic Lipid and Noncoding Plasmid DNA Results in the Induction of Cytotoxic T Cells and Systemic Tumor Elimination," *Mol. Ther. 6*:519-527, Academic Press (October 2002)
	AT	12	Singh, M., and O'Hagan, D., "Advances in vaccine adjuvants," *Nat. Biotechnol. 17*:1075-1081, Nature America Publishing (1999)

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	AO						Yes No
	AP						Yes No

OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

	AR	13	Spier, R.E., "International Meeting on the Nucleic Acid Vaccines for the Prevention of Infectious Disease and Regulating Nucleic Acid (DNA) vaccines," *Vaccine 14*:1285-1288, Elsevier (1996)
	AS	13	Vahlsing, H.L., *et al.*, "Immunization with plasmid DNA using a pneumatic gun," *J. Immunol. Methods 175*:11-22, Elsevier (1994)
	AT	13	Yamamoto, S., *et al.*, "DNA from Bacteria, but Not from Vertebrates, Induces Interferons, Activates Natural Killer Cells and Inhibits Tumor Growth," *Microbiol. Immunol. 36*:983-997, Japanese Society For Bacteriology (1992)

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	AN						Yes No
	AO						Yes No
	AP						Yes No

OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

	AR	14	Yamamoto, T., *et al.*, "Lipofection of Synthetic Oligodeoxyribonucleotide Having a Palindromic Sequence of AACGTT to Murine Splenocytes Enhances Interferon Production and Natural Killer Activity," *Microbiol. Immunol. 38*:831-836, Japanese Society For Bacteriology (1994)
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